

### **REMARKS**

The Examiner is requested to thoroughly consider Applicant's remarks in their entirety.

#### **I. The claims**

Pursuant to this paper, claims 1-21, 23 and 25-40 are pending. Claims 1-16 are presently withdrawn as a result of being deemed to be directed to a non-elected inventions and claims 21, 23, 26, 28, 31 and 33-35 are presently withdrawn as being drawn to non-elected species. Claims 22 and 24 have been canceled herein. Accordingly, claims 17-20, 25, 27, 29, 30, 32 and 36-40 are presently under examination.

Independent claims 17, 18, 25 and 29 have amended herein. Support for the amendments is found for example: in ¶136; ¶141; also at page 3, l. 28-29; and in originally filed claim 36, of the originally filed specification.

No new matter has been added by any of the amendments made herein.

#### **II. Claim rejections under 35 U.S.C. §101**

Claims 18, 19, 22, 24, 29, 30, 32 were rejected under 35 U.S.C. §101 as allegedly encompassing non-statutory subject matter, namely human beings. (Present Office Action, ¶4.)

The present rejection of the claims is overcome for the following reasons.

Each of the independent claims has been amended to recite that the subject cell is a plant cell. Accordingly, the scope of the claims no longer encompasses non-statutory subject matter.

In view of the above, withdrawal of the present rejection of the claims is requested.

### **III. Claim rejections under 35 U.S.C. §112 – enablement requirement**

Claims 18-20, 22, 24, 29, 30, 32, 36, and 40 were rejected for alleged lack of enablement under 35 U.S.C. §112, paragraph 1. (Present Office Action, ¶6.) However, the Examiner has pointed out that “[t]he claims are only enabled for cell wherein a pre-selected DNA sequence is excisable from the cellular genome in response to the presence in the cell of a nucleic acid complementary to the mRNA encoding the repressor protein.” (Present Office Action, page 5, l. 5-7).

The present rejection of the claims is overcome for the following reasons.

The claims have been substantially limited, namely to the plant embodiments wherein RNA silencing against the RNA transcript of the recited repressor protein is triggered by an unmodified viral double-stranded RNA molecule. Support for the present embodiment is found, for example, in ¶¶136 and 141 of the originally filed specification.

As pointed out in the originally filed specification at ¶¶5 and 120 (and well known in the art at the time of filing as shown by the incorporated NPL documents related to plants), in plant cells long double-stranded RNA triggers RNA silencing as a result of being processed into short siRNA molecules by an RNase III enzyme, Dicer.

In addition ¶¶131 and 136 make it absolutely clear that the originally filed specification is teaching that sequences are selected according to the invention such that the siRNAs produced from long double stranded RNA in organisms such as plants (now claimed), will be complementary to the desired target. Thus, it is submitted that the presently amended claims are now within the scope that the Examiner has stated is enabled.

In addition, it is clear and was well known (see, e.g., Goselle et al. (2002) The Plant Journal 32: p. 859-66 – *of record*) that genetically engineering double stranded RNA viruses (thus long double-stranded RNA) to include anywhere sequence complementary to a cellular RNA transcript sequence can be used to silence the cellular RNA transcript upon infection of the cell by the virus. This clearly supports enablement of the presently claimed cellular excision system and methods *wherein* the double stranded virus is not modified, but, instead, the cell is modified such as the gene for the

repressor protein (§§131 and 136 of the originally filed specification) or for transitive RNA silencing (§§138, 139 and 141 of the originally filed specification), so that the unmodified viral double-stranded RNA will trigger silencing against the repressor protein RNA transcript.

In view of the above, withdrawal of the present rejection of the claims for alleged lack of enablement under 35 U.S.C. §112, first paragraph is requested.

#### **IV. Claim rejections under 35 U.S.C. §103(a)**

Claims 17-20, 22, 24, 25, 27, 29, 30, 32, and 36-40 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent No. 5,723,765 to Oliver et al. ("Oliver"), in view of Porter (Trends Genet, 1998, 14: 73-79). (Present Office Action, ¶8.)

The present rejection of the claims is overcome for the following reasons.

Nothing in either of Oliver or Porter teaches or even remotely suggests a plant cell as now recited in the presently amended claims that includes the recited conditional excision system and that includes further modification of either (i.) the gene for the repressor protein (§§131 and 136 of the originally filed specification) to include sequence complementary to an unmodified plant viral dsRNA or (ii.) modified for transitive RNA silencing (§§138, 139 and 141 of the originally filed specification), so that in either case an unmodified plant viral double-stranded RNA will trigger silencing against the repressor protein RNA transcript. It is noted that these two types of modifications correspond to the "means" for the particular claims presented in such form. Moreover not even the slightest motivation is presented for such a system by any of the prior art.

The Examiner is also reminded that the federal courts have pointed out that most inventions are new combinations of elements known in the art. Accordingly, it is cautioned that the test of non-obviousness is not and has never been whether the individual elements of an invention were already known.

In view of the above, withdrawal of the present rejection of the claims under 35 U.S.C. §103(a) is requested.

**V. Conclusion**

Pursuant to this paper, Applicant submits that elected claims 17-20, 25, 27, 29, 30, 32 and 36-40 are in condition for further examination and allowance, which action is hereby requested.

If upon considering this paper, the Examiner still considers any claim to be unallowable, Applicant respectfully requests that the Examiner telephone Applicant at the number below to discuss any issues that are considered to remain.

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Respectfully submitted,

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